

## **REMARKS**

Applicant appreciates the Examiner's review of the present application. The Examiner has maintained its rejection of claims 1, 5-15, 23, 24, 35, and 38-42 based upon a combination of U.S. Patent No. 6,740,041 (Faulkner et al) read in combination with U.S. Patent No. 4,631,676 (Pugh) and US Publication No. 2002/0137082 (Lewandrowski). Examiner has rejected the balance of the claims by combining Faulkner, Pugh, and Lewandrowski with other references, including U.S. Patent No. 6,234,969 (rejection of claims 2-4 and 36), U.S. Patent No. 4,195,643 (rejection of claims 16, 17, and 37), U.S. Patent No. 6,803,197 (rejection of claims 18-20), and U.S. Patent No. 6,086,538 (rejection of claims 21, 22, 25-32, and 43-47). Before substantively addressing Examiner's rejections, Applicant would like to present a brief overview of its invention, in order to provide a framework within which to properly analyze the relevant art.

### *Overview of the Present Invention*

The present invention is directed to methods for effectively integrating various known bone measurement techniques into a holistic diagnosis and treatment paradigm. See Specification, 0009. Applicant's patent specification expressly recognizes that the prior art discloses a variety of tests, including bone characteristic measurement devices (ultrasound and x-ray), biochemical marker tests, and gait measurement tests. It further recognizes that some protocols do exist for the diagnosis and treatment of osteoporosis, but that such protocols are primarily based on a patient's age, weight, postmenopausal status, and estrogen use. See Specification, 0010.

As noted in the specification, a key problem not addressed by the art is how best to integrate disparate data from gait measurements, biochemical marker tests, and bone characteristic measurements. As of the filing date of the present application, the art did not define when certain tests should be performed or how test results should be integrated. At each visit, should a patient be subjected to a gait measurement? At each visit, should a patient be subjected to a biochemical marker test? If not, when should a patient be subjected to such tests? Conventional diagnostic processes did not establish when, or if, a patient should undergo one, two, three, or more diagnostic tests in combination. The processes of the present application,



however, optimally choose only those patients whose biological state requires them to undergo two or three diagnostic tests. These fundamental treatment processes are simply not defined in the art.

#### *Applicant's Claim Amendments*

Applicant has amended pending claim 1, canceled claims 35-43, and has not amended claims 2-34 and 44-47. The purpose of the claim amendments and cancellations is to focus the prosecution on a specific diagnosis protocol. In particular, in claims 1-34, the protocol requires:

1. First measuring a bone characteristic level in a bone of the patient to yield a first score having a value;
2. Then, based upon the value of the first score, conducting a gait analysis on the patient to yield a first gait characterization;
3. Then, based upon the value of the first score and the first gait characterization, measuring a bone marker concentration in at least one body fluid of the patient to yield a first bone marker level having a value; and
4. Finally, prescribing a therapy based on at least one of the first score, the first gait characterization and the bone marker level value.

More specifically, in claims 44-47, the protocol requires:

1. First, measuring a bone characteristic level in a bone of said patient to yield a T-score having a value;
2. Then, if the T-score is abnormal, conducting a gait analysis to yield a gait characterization;
3. Then, if the gait characterization is abnormal, measuring a bone marker concentration in at least one body fluid of the patient to yield a bone marker level having a value;
4. Then, prescribing a therapy based on at least one of the gait characterization, the T-score, and bone marker level; and
5. Finally, designating a future time to repeat the measurement of a bone



characteristic level, gait analysis, and measurement of a bone marker concentration.

Applicant agrees that bone characteristic level measurements, gait characterizations, and bone marker level measurements exist in the art. However, as amended, the claims are directed to a specific protocol for how best to conduct measurements and diagnosis a patient, which, as noted below, has not been disclosed in the art.

#### *Examiner's Rejections*

Applicant respectfully disagrees with Examiner's conclusion that the pending claims are obvious under 35 U.S.C. Section 103(a) based upon the combination of four references. Central to the Examiner's conclusion is the following observation:

"As for the order and the extent of the analysis of the measurements that are done, they result in the same end result of the characterization of risk factor. The order in which the tests are done would not make a difference. It would be obvious to one skilled in the art at the time of the invention to try and get the most accurate and through [thorough] diagnosis in order to prescribe the most proper therapy and to take into account the results of previous measurements. Faulkner et al.'s invention most embodies this with the ability to input other results and factors of osteoporosis into the computer."

Examiner has dismissed any potential novelty in a treatment process that defines how various known measurement techniques can be optimally integrated together. However, Examiner provides no basis for making this conclusion. The cited art recognizes that these various measurement techniques are, in fact, measuring different factors, namely the density of bone, the mobility and balance of a patient, and the rate of bone formation or resorption. The key technical question is—how should one integrate these varied measurements? The prior art does not answer this question.

Examiner argues is that it does not matter because the test order "would not make a difference". However, such an answer belies the fact that these tests require the expenditure of time and resources, not to mention discomfort on the part of patients. It is preferred that only those patients which require all three measurements (testing different aspects of a patient's



biological state) actually undergo all three diagnostic tests. It is also preferred that those patients who do not require all three measurements only undergo the minimum number of diagnostic tests required. Therefore, whether you undergo all one, two, or three tests certainly matters. Under Examiner's interpretation, a system that required every patient to undergo all three measurements operates the same as a system that optimally chose only those patients whose biological state required them to undergo all three diagnostic tests. There is nothing in the art to support that conclusion.

Applicant's claims recognize that the test order does make a difference and, further, proposes a specific protocol for ordering the diagnostic tests. Applicant's invention expressly provides for the bone characteristic level measurement to be the threshold test. It only requires a gait measurement based on the value of that specific measurement. Furthermore, it only requires a bone marker concentration measurement based on the value of both the gait measurement and bone characteristic level measurement. This diagnostic process avoids having all patients be subjected to all three tests and focuses scarce health care resources on those patients whose biological state warrants actually be subjected to all three tests.

As a final note, even adopting Examiner's expansive interpretation of Faulkner, the Faulkner reference does not define when, or if, to combine various diagnostic tests. In fact, Examiner's argument indicates that Faulkner teaches that one should *always* engage in a gait measurement and biochemical marker measurement in order to determine a patient's absolute fracture risk. Nothing in Faulkner, or any of the other references, indicates that certain tests are optional or dependent upon the value of previously conducted tests. Rather, as Examiner's argument notes and Faulkner allegedly represents, the only way to get to an evaluate of a patient's fracture risk is to take into account **all** patient data, thereby expressly teaching away from the selective diagnostic methods of the present invention.

Applicant respectfully submits that the Examiner's use of three, and in some cases four, separate references to reject the pending claims, when none of those references suggest or even imply the desirability of such a combination, is plainly improper. Because the diagnostic protocol of claims 1 and 44 are novel and not obvious, dependent claims 2-34 and 45-47 are also novel and not obvious. Applicant submits that this case is in form for allowance.



**Request for a one month extension**

Applicant requests a one month extension of time. The three month statutory response period ended on May 12, 2007. Applicant is submitting the present response on June 12, 2007 and, therefore, requests a one month extension of time. Applicant is electronically submitting the requisite \$120 fee via the US PTO's PAIR website on June 12, 2007.

Respectfully submitted,



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